URGENT: MEDICAL DEVICE RECALL -- Samaritan® 300/300P PAD

September 11, 2012

Dear Valued Customer:

This letter is to inform you of a voluntary global correction to certain of **HeartSine Technologies, Ltd.'s Samaritan® 300/300P PAD public access defibrillators**. This correction will address two separate issues that could affect your ability to deliver therapy to a patient in a sudden cardiac arrest (SCA) event, if needed. By completing the actions described in this letter, your device(s) will have a new battery to be held in reserve and the most current version of the software, which includes the latest battery management software involved in this correction. **HeartSine's records indicate you have received a product that is affected by this action.**

To ensure that you are always able to deliver therapy during a sudden cardiac arrest event, as soon as possible after we receive your response form indicating where you would like your equipment shipped, we will arrange to supply you: (1) a 1500 mAh PAD-PAK to be held in reserve in the zippered pouch on the back of your device; (2) a data cable and CD so that you can upgrade the current version of the device software; (3) a hang tag for your device that will instruct users how to install the reserve PAD-PAK should the current PAD-PAK appear to lack sufficient battery power during a patient event; and (4) a new user manual to reflect the software version you will now be using.

Based on information available to date, certain Samaritan 300/300P PAD devices may experience one or both of the following conditions that could affect your ability to deliver therapy to a patient in a SCA event, if needed:

- ***Issue 1*** **(On/Off Issue)**:
  The device may turn itself on and off without input from the user. When this occurs, the *normal sequence of audible instruction prompts that occurs when the device is turned on will be emitted from the device. If the device does not detect that the audible prompts are followed (e.g., a patient is connected to the electrodes to allow the device to read the patient's ECG and start the normal sequence of events), the device will automatically switch off after 10 minutes to save power. This sequence of on-off events can happen repeatedly or intermittently. If this condition is undetected, the battery will eventually become completely depleted. In worst-case situations, it is possible that the battery could be depleted below the minimum battery capacity to allow for the delivery of therapy within a week.* However, a device experiencing this issue will be capable of delivering therapy provided that an adequate power source is available. As further explained below, a 1500 mAh PAD-PAK to be held in reserve is provided for this purpose.

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Devices potentially subject to the on/off issue were manufactured between August 2004 and December 2010 and have a warranted life of 7 years.

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- **Issue 2 *(Battery Management Software Issue)*:**
  Certain Samaritan 300/300P PAD devices containing early versions of the battery management software may misinterpret a temporary drop in battery voltage as signaling a low battery. This issue will result in the device prematurely displaying the low battery warning and turning itself off even though sufficient battery capacity remains. This may occur when the device performs its weekly self-test, or when the device is turned on, or when the device is preparing to deliver a shock, or after delivering a shock. If the low battery warning is triggered due to this issue, the device will have sufficient power to deliver multiple shocks, but it is possible that the device may not deliver any shocks, or it may only deliver one shock before turning itself off. If this occurs, delivery of any subsequent shocks may be delayed and would likely only be delivered at the lowest energy level of 150 Joules. Once the device has experienced this condition, it is more likely to experience it again.

  This condition can occur when the installed PAD-PAK has already been partially depleted due to normal battery depletion or where the installed PAD-PAK is an 800 mAh capacity battery. This software version was distributed until the end of December 2010. Devices containing software versions 1.4.2 / 3.2.0 or higher are not susceptible to this issue.

Samaritan® 300/300P PAD devices with the following serial numbers inclusive are affected by one or both these issues:

- 0400000501 to 0700032917
- 08A00035000 to 10A00070753 ←
- 10C00200000 to 10C00210106

Please note that a 'typo' error has been corrected in this serial number (it was 10A0070753). Please ensure this does not affect any other devices in your possession.

No other HeartSine automated external defibrillator products are affected by either issue. No deaths or injuries have been reported to date associated with the on/off issue. To date, HeartSine has received five reports of death for which the company has not been able to rule out the possibility that the events may have been related to the battery management software issue. This recall is being made with the knowledge of the U.S. Food and Drug Administration.

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Please take the following actions to ensure that you are able to provide therapy in the event that a SCA event occurs:

1. **DO NOT** remove your device(s) from service.
2. If necessary, relocate the Samaritan® 300/300P PAD to an area where the audible prompts would be heard if initiated. **If the device turns itself on and off OR if your device displays a Low Battery Warning before the expiry date labelled on the PAD-PAK in the device, contact HeartSine Technologies, at 1-877-877-0147 immediately so that we may make sure that you have the ability to provide therapy in the future.**
3. Immediately increase the frequency of your device checks to daily to confirm that the Samaritan 300/300P PAD is operable and in ready standby mode as indicated by a flashing green LED (see the HeartSine Samaritan® PAD SAM 300/300P User Manuals).

Status Indicator light

4. Confirm that the LED light is flashing green. If the LED is red or unlit, contact HeartSine Technologies, at **1-877-877-0147** immediately so that we may send you a replacement unit.
5. Return the attached response form indicating that you have received and understand this communication and indicating where you would like HeartSine to ship your equipment (*i.e.*, reserve PAD-PAK, CD, data cable, user manual and hang tag).
6. When you receive the 1500 mAh PAD-PAK, insert it in the zippered pouch on the back of the Samaritan 300/300P PAD soft carrying case so that it may be held in reserve if needed. **MAKE SURE YOU ALWAYS HAVE A RESERVE PAD-PAK ON HAND.**
7. When you receive the hang-tag, attach it to the handle of the Samaritan 300/300P PAD soft carrying case to alert a first responder that they may need to replace the installed depleted PAD-PAK with the reserve PAD-PAK contained in the zippered pouch. Instructions for replacing the PAD-PAK are provided on the hang-tag.
8. When you receive the CD, data cable and User Manual, your device must be connected to a USB port in your computer so that the current version of the software can be downloaded. The software can also be downloaded from http://www.heartsine.com/recall/software_updates. Either the CD or the link will automatically update your device to the appropriate version of the battery management software. Replace the originally supplied User Manual, stored in the soft carry case, with the new copy supplied with this field action.
9. **If you need your device in a sudden cardiac arrest event and the LED is red or unlit**, replace the PAD-PAK with the reserve PAD-PAK according to the instructions on the hang tag. Once the reserve PAD-PAK has been inserted, you will be able to deliver therapy. Following the event, contact HeartSine Technologies, at **1-877-877-0147** immediately so that we may make sure that you have the ability to provide therapy in the future.

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If you have further distributed this product, please notify your customers at once of this communication or provide your consignee list in an Excel file and we will send a direct notification to your customers within that consignee list that have not already been notified. You can email this customer list directly to support@heartsine.com. If you do not have email capabilities please call 1-877-877-0147 for alternative ways to supply your customer list. This recall should be carried out to the user level. Your assistance is appreciated and necessary to ensure that you are able to provide therapy to SCA patients.

Please complete and return the enclosed response form as soon as possible. If you have any questions, call HeartSine Technologies at **1-877-877-0147** or your service representative.

At HeartSine, the lifesaving legacy we began in 1967 remains a passion that drives all of our employees today. We are committed to working with you in partnership in providing public safety at the highest levels, and we thank you for your business and continued support. We regret the inconvenience this may cause you. We value you and your patients and appreciate your understanding as we work to ensure that we are providing you with the life-saving devices you have come to rely upon.

Sincerely,

Uel McChesney
President and CEO
HeartSine Technologies, Ltd.

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RESPONSE FORM

Please assist us in making this Medical Device Recall Notification follow-up process efficient and convenient for you by completing and returning this form to HeartSine via email, or fax; which serves as a confirmation that you have received and understand this notification. Also, please indicate where you would like your equipment shipped.

A cover sheet is not required. You can also download this form on our website at www.HeartSine.com/recall

FAX: 1-888-912-7344
E-MAIL: **support@heartsine.com**

If you have questions, please call HeartSine at 1-877-877-0147 between 8:00 am to 5:00 pm ET Monday through Friday.

Please complete this form by checking the applicable boxes indicating that you understand and have taken or will take the recommended actions.

- □ We have checked our device(s) and the low battery warning is not displayed.
- □ We have relocated the device(s) to an area where the audible prompts would be heard if initiated.
- □ We are increasing our device status checks to daily.
- □ Upon receipt, we will
  - Place the reserve 1500 mAh PAD-PAK™ in the zippered portion of the soft carrying case.
  - Place the hang tag on the soft carrying case handle
  - Update the device(s) software using the supplied CD or the website download, using the data cable supplied.
  - Replace the originally supplied User Manual, stored in the soft carrying case, with the new copy supplied with this field action.

Device serial number(s)	
Facility Name:	
Facility Address:	
□ Check if you would like the equipment sent to the above address or provide address below	

Completed By:	**Title:**
Signature:	**Date:**
Phone No:	**Facsimile No:**
Email:	
Preferred form of contact	□ Email □ Phone □ Fax

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